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- Omori, Kenji  
Kita-ku, Osaka-shi, Osaka-fu (JP)
- Honda, Minoru  
Kita-ku, Osaka-shi, Osaka-fu (JP)
- Futagawa, Hitoshi  
Kita-ku, Osaka-shi, Osaka-fu (JP)

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(71) Applicant: **NIPRO CORPORATION**  
Osaka-shi Osaka 531 (JP)

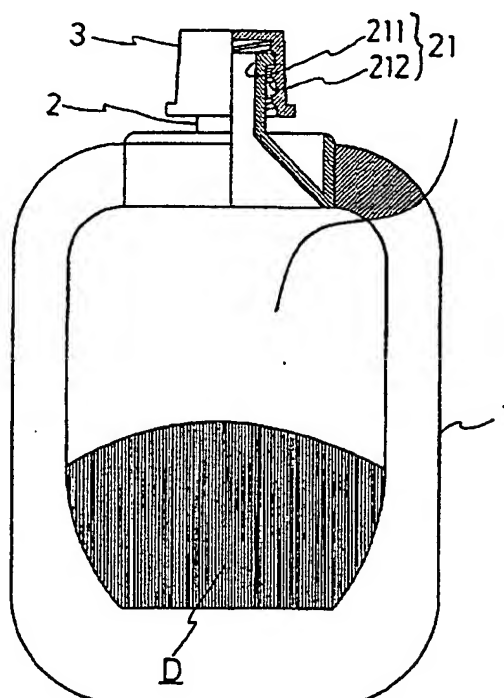
(74) Representative: **VOSSIUS & PARTNER**  
Siebertstrasse 4  
81675 München (DE)

(72) Inventors:  
• Takimoto, Hiroaki  
Kita-ku, Osaka-shi, Osaka-fu (JP)

**(54) Small bag-shaped drug container**

(57) A bag-shaped drug container comprises a bag-shaped container body 1 made of a flexible film, and a mouth 2 provided at one end of the container body 1. The mouth 2 is provided on a side of an open end thereof with a Luer locking means 21 to liquid-tightly connect it with a tip of a syringe, and closed by a closing means such as cap 3 or a male Luer portion.

fig. 1



## Description

[0001] The present invention relates to a small bag-shaped drug container and, more particularly, to a small bag-shaped drug container suitable for almost insoluble or insoluble drugs. Further, the present invention relates to a small bag-shaped drug container, which enables a drug to be easily and completely dissolved or suspended in spite of a small amount of a solution.

[0002] Drugs which are easily degenerated by moisture or oxygen have conventionally been administered in the form of a liquid drug prepared just before use by mixing it with a solution. In order to prepare the liquid drug, there have widely been used a so-called syringe method comprising the steps of injecting a solution into a vial containing a dried drug with a syringe, and then drawing the resultant liquid drug into the syringe, or a method employing a double ended needle to communicate a solution container with a drug container. Recently, in order to remove troublesome dispensation, double chamber type prefilled syringes have been put into practical use. Such a prefilled syringe contains a drug in a drug chamber and a solution in a solution chamber, which are adapted to be communicated with one another by communicating means such as a bypass or a built-in connecting needle to dissolve the drug in the solution.

[0003] The syringe method is used for preparation of a liquid drug less than about 10 ml, but it is troublesome in dissolving operation. Further, in case that a drug such as a subcutaneous injection is required to be dissolved or suspended in a small amount of the solution, it is extremely difficult to perform the dissolving operation in the vial. In addition, in case of insoluble or hardly insoluble drugs, it is required to repeatedly transfer a mixture of the solid medicine and the solution from the syringe to the vial or vice versa in order to achieve complete dissolution or suspension. However, it is very difficult to perform such dissolving operations without producing foaming.

[0004] The above troublesome dispensation can be avoided by use of the method of employing a double-ended needle or the double-chamber type prefilled syringes. However, it is very difficult with the method of employing a double-ended needle to dissolve insoluble or hardly insoluble drugs in the solution without foaming since the mixture of the solid medicine and the solution must be repeatedly transferred from the syringe to the vial or vice versa in order to achieve complete dissolution or suspending. Similarly, it is very difficult with the double-chamber type prefilled syringe to perform dissolving operation without foaming since the mixing can be performed only by shaking of the syringe.

[0005] It is therefore an object of the present invention to provide a bag-shaped drug container, which makes it possible to easily and completely dissolve or suspend a drug in a solution even if the drug is almost insoluble or insoluble or even if the dissolution or suspension is carried out with a small amount of the solution, as well

as to minimize foaming of the drug solution during dissolving or suspending operation, and to prevent the working site from being soiled with the drug solution at the time of recovery of the dissolved or suspended solution into the syringe.

[0006] The above objects of the present invention are solved by constituting a drug container with a flexible bag-shaped container to make it possible to press and rub the drug container with hands, and further providing a mouth of the container with means for fixing a tip of a syringe to the mouth of the container to prevent the syringe from falling off from the mouth of the container during pressing and rubbing.

[0007] According to the present invention, there is provided a small bag-shaped drug container comprising a container body formed into a bag with a flexible film and a mouth provided at one end of said body, and a Luer locking means provided at an open end of said mouth and being liquid-tightly connectable to a tip of a syringe.

[0008] The above film may be composed of a single layer of polyolefine, or multi-layers including an innermost layer of polyolefine. Further, the film may be a film of water permeability and oxygen permeability, or a film of water impermeability and oxygen impermeability. However, if the film is composed of a single layer film of polyolefine or a film of water permeability and oxygen permeability, it is necessary to package the container in a packaging medium with water impermeability and oxygen impermeability.

[0009] The container body may be composed of a front film having water permeability and oxygen-permeability and a rear film having water impermeability and oxygen-impermeability and partitioned into two chambers by an easily peelable tender sealing portion provided at a position close to the mouth, one of two chambers being communicated with the mouth, while other chamber being uncommunicated with the mouth. In this case, the front film of the chamber uncommunicated with said mouth may be provided with an easily peelable, water-impermeable and oxygen-impermeable cover film, and the chamber communicated with the mouth may be charged with a drug.

[0010] The terms "water-impermeability and oxygen-impermeability" used herein mean properties that can not be permeated by water and oxygen. The terms "water-permeable and oxygen-permeable" used herein mean properties that can be permeated by water and oxygen and includes the properties that are almost impermeable to water and oxygen.

[0011] The present invention will be explained below in detail, making reference to the accompanying drawings, which show, by way of example only embodiments thereof.

Fig. 1 is a partially cutaway plan view of a bag-shaped drug container illustrating one embodiment of the present invention;

Fig. 2 is a diagram illustrating the bag-shaped drug container of Fig. 1 packaged in a packaging medium;

Fig. 3 is a longitudinal cross section of a bag-shaped drug container illustrating another embodiment of the present invention;

Fig. 4 is a diagram illustrating a way to use the bag-shaped drug container of the present invention.

**[0012]** As illustrated in Fig. 1, a bag-shaped drug container of the present invention comprises a bag-shaped container body 1 made of a flexible film, and a mouth 2 provided at one end of the container body 1. The mouth 2 is provided on a side of an open end thereof with a Luer locking means 21 to liquid-tightly connect it with a tip (denoted by a reference sign C in Fig. 4) of a syringe provided at a distal end thereof. The mouth 2 is closed by a closing means such as cap 3 or a male Luer member (not illustrated in the drawings).

**[0013]** The bag-shaped drug container of the present invention is a drug container suitable for use in syringe method widely used for preparation of a drug solution with a small amount of less than about 10 ml. Thus, the container body 1 is so designed to have a capacity of not more than 10 ml and, preferably, not more than 5 ml.

**[0014]** The film that forms the container body 1 may be a single layer film of polyolefine such as polypropylene, polyethylene, polyethylene terephthalate (PET), or a multi-layer film including an innermost layer of polyolefine. The film may be permeable to water and oxygen or impermeable to water and oxygen. Preferred multi-layer films include laminated films comprising a deposited silica layer which is almost impermeable to moisture or oxygen, or aluminum foil-laminated films laminated with a water-impermeable and oxygen-impermeable aluminum foil. The laminated films including a deposited silica layer comprises, for example, multilayer films including an outermost layer of a copolymer of polyethylene (PE) and polypropylene (PP) and an innermost layer of polyethylene, and having a structure of (PE + PP) / SiO<sub>2</sub> / PET / SiO<sub>2</sub> / PE. In that case, the outermost layer may be of polyethylene. Preferred aluminum foil-laminated films comprises, for example, multilayer films including an outermost layer of polyethylene terephthalate and an innermost layer of polyethylene and having a structure of PET/aluminum foil/PE. In that case, one or more other plastic layers may lie between aluminum foil and PE.

**[0015]** If the film is a single layer film of polyolefine or a film with water-permeability and oxygen-permeability, the whole container is required to be packaged in a water-impermeable and oxygen-impermeable packaging medium 4, as illustrated in Fig. 2. Preferred packaging medium for this purpose includes, for example, an aluminum foil laminated film having a structure of PET/aluminum foil/PE.

**[0016]** The container body 1 may be made of a front film 11 having water-permeability and oxygen-permea-

bility and a rear film 12 having water-impermeability and oxygen-impermeability, as illustrated in Fig. 3. In this case, the front film 11 is required to be covered with a water-impermeable and oxygen-permeable cover film 5. To this end, the container body 1 is partitioned at a position close to the mouth 2 thereof into two chambers, i.e., a first chamber 13 communicated with the mouth 2 and a second chamber 14 uncommunicated with the mouth 2, by an easily peelable tender sealing portion 6. In this case, it is required to use a portion of the front film 11 on the tender sealing portion 6 as a bonding area for the cover film 5. A drug D is contained in the second chamber, i.e., chamber 14 covered with the cover film 5 and uncommunicated with the mouth 2.

**[0017]** The mouth 2 is a cylindrical member generally made of the same resin as that of the innermost layer of the container body 1, and provided at an open end thereof with a Luer locking means 21. The Luer locking means 21 is connecting means, which performs Luer connection concurrently with locking connection (e.g., screw engagement). The Luer locking means used for this purpose generally comprises, for example, a female Luer portion 211 formed by decreasing tapering a diameter of a lumen of the mouth 2 according to a shape of a male Luer portion (designated by C1 in Fig. 4) of a needle connecting portion of a syringe, and a male locking portion 212 provided on an outer wall of the mouth 2 for engagement with a female locking portion (designated by C2 in Fig. 4) of the needle connecting portion of the syringe, as illustrated in Figs. 1-3.

**[0018]** The bag-shaped drug container of the present invention is used in the manner explained below with reference to Fig. 4.

**[0019]** Firstly, there are prepared a bag-shaped drug container FB and a Luer locking type syringe provided at a distal end thereof with a Luer locking type needle-connecting portion C (hereinafter referred to as a "tip"). The tip C of the syringe S is fit in the mouth 2 of the drug container FB. Then, the syringe S is turned in the direction indicated by an arrow A for engagement of the tip C with the Luer locking means 21, whereby reliably connecting the syringe S to the mouth 2 of the bag-shaped drug container FB (Fig. 4(a)). As illustrated in Fig. 4(b), - by pressing a plunger P of the Syringe S toward the tip C, a solution in the syringe S is injected into the drug container FB. The container body 1 is then pressed and rubbed with hands to dissolve or suspend the drug in the solution. After complete dissolution or suspension, the resultant drug solution or suspension is drawn into the syringe S by pulling the plunger P away. Then, the syringe S is turned in the direction indicated by an arrow B in Fig. 4 (c), whereby the tip C is disengaged from the Luer locking means 21. By fitting a hollow needle on the tip C of the syringe S, the syringe S is ready for injection.

**[0020]** As will be understood from the above, the bag-shaped drug container according to the present invention makes it possible to dissolve or suspend the drug in the solution by pressing and rubbing the container

body with hands. Further, the syringe is prevented from separation from the drug container during pressing and rubbing operation, thus making it possible to easily and completely dissolve or suspend the drug in the solution even if the drug is almost insoluble or insoluble or even if the dissolution or suspension is carried out with a small amount of solution. In addition, it is possible to minimize foaming of the drug solution during dissolving or suspending operation. Also, it is possible to prevent the working site from being soiled with the drug solution at the time of recovery of the dissolved or suspended solution into the syringe.

and oxygen-impermeable cover film, and the chamber uncommunicated with said mouth being charged with a drug.

#### Claims

1. A small bag-shaped drug container comprising a container body formed into a bag with a flexible film and a mouth provided at one end of said body, and a Luer locking means provided at an open end of said mouth and being liquid-tightly connectable to a tip of a syringe.
2. The bag-shaped drug container according to claim 1, wherein said film is a single layer film of polyolefine.
3. The bag-shaped drug container according to claim 1, wherein said film is a multilayer film including an innermost layer of polyolefine.
4. The bag-shaped drug container according to claim 2, wherein said container is packaged in a packaging medium with water impermeability and oxygen impermeability.
5. The bag-shaped drug container according to claim 3, wherein said film is water permeable and oxygen permeable, and wherein said container is packaged in a packaging medium with water impermeability and oxygen impermeability.
6. The bag-shaped drug container according to claim 1, wherein said film is water impermeable and oxygen impermeable.
7. The bag-shaped drug container according to claim 1, wherein said container body is made of a front film having water-permeability and oxygen-permeability and a rear film having water impermeability and oxygen-impermeability, and partitioned into two chambers by an easily peelable tender sealing portion provided at a position close to a mouth thereof, one of said chambers being communicated with said mouth, while other chamber being uncommunicated with said mouth, the front film of the chamber uncommunicated with said mouth being covered with an easily peelable, water-impermeable

fig. 1

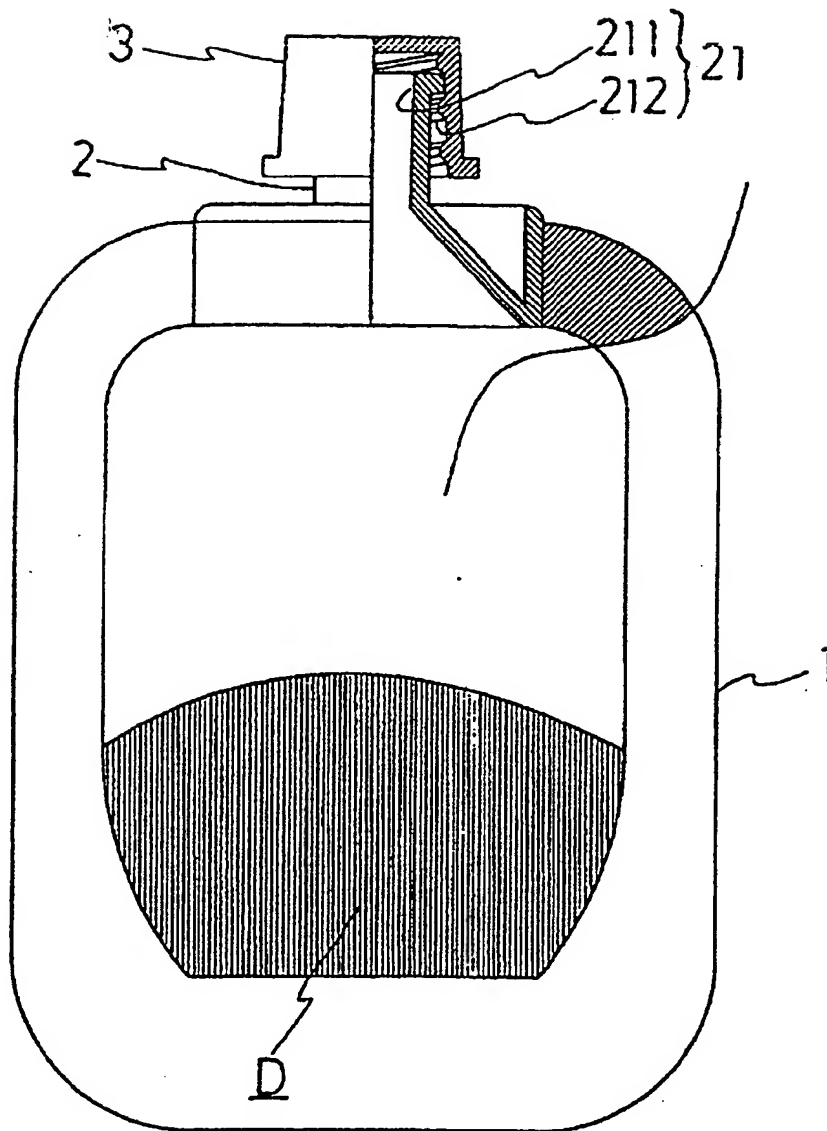
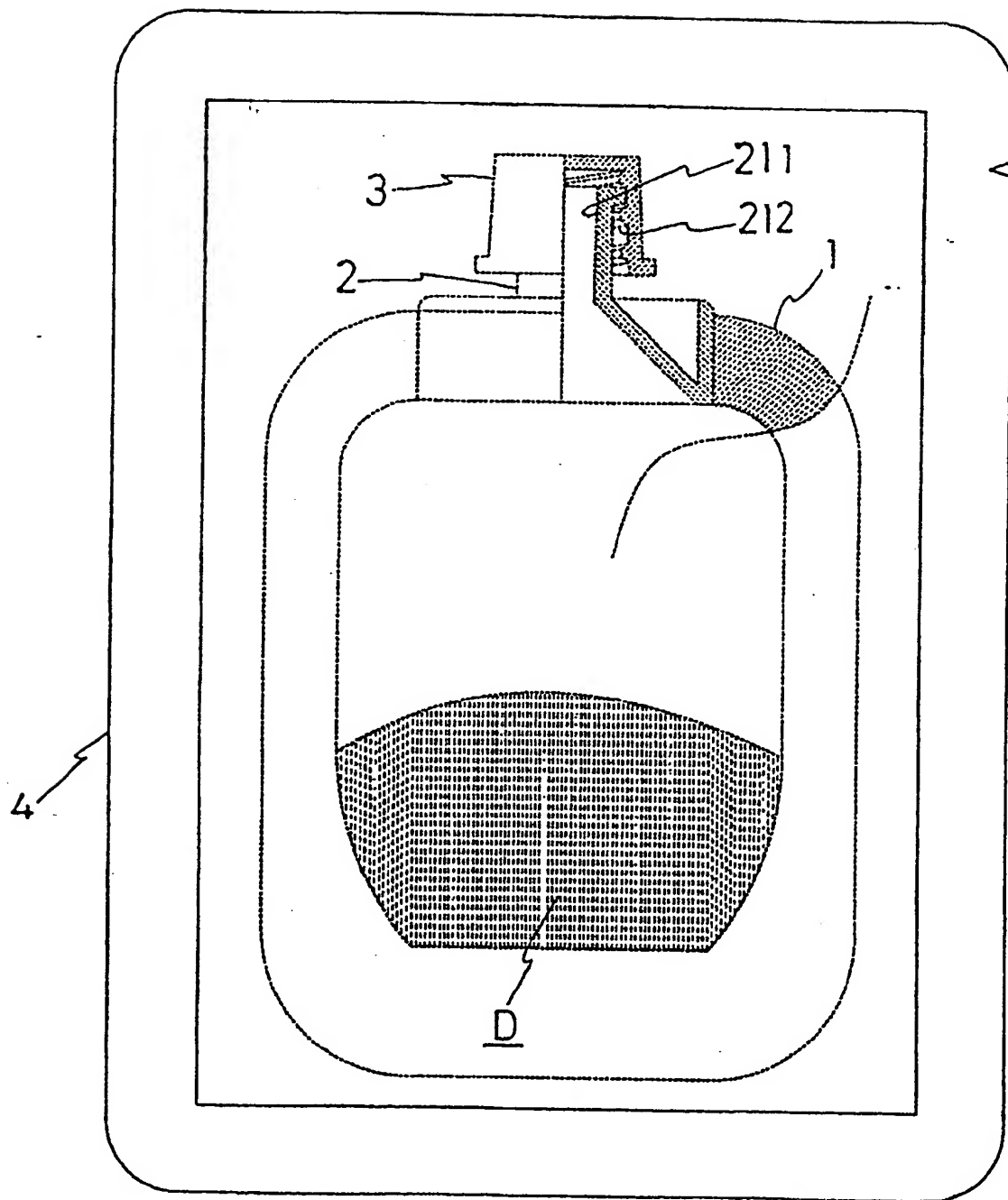


fig. 2



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fig. 3

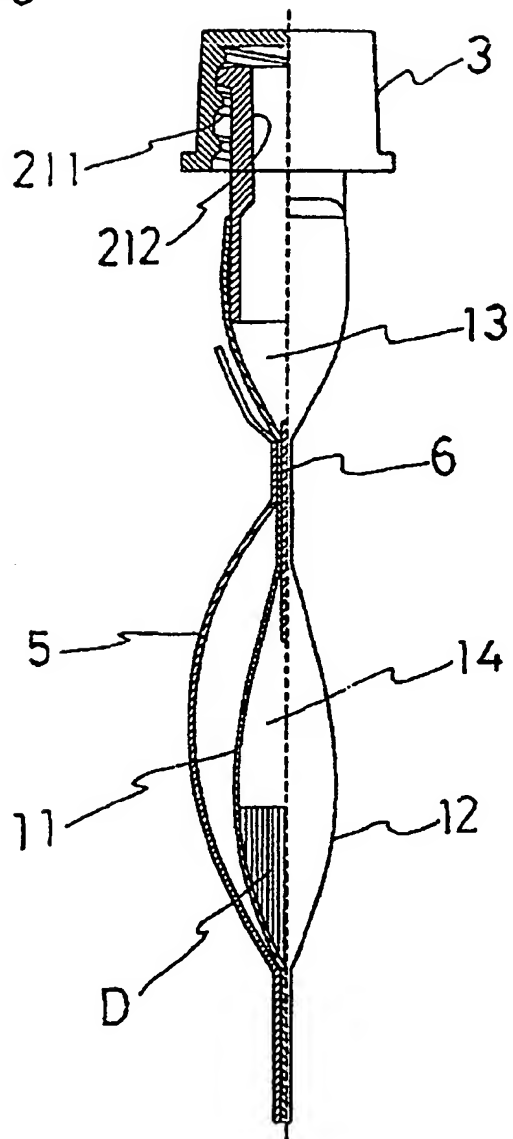
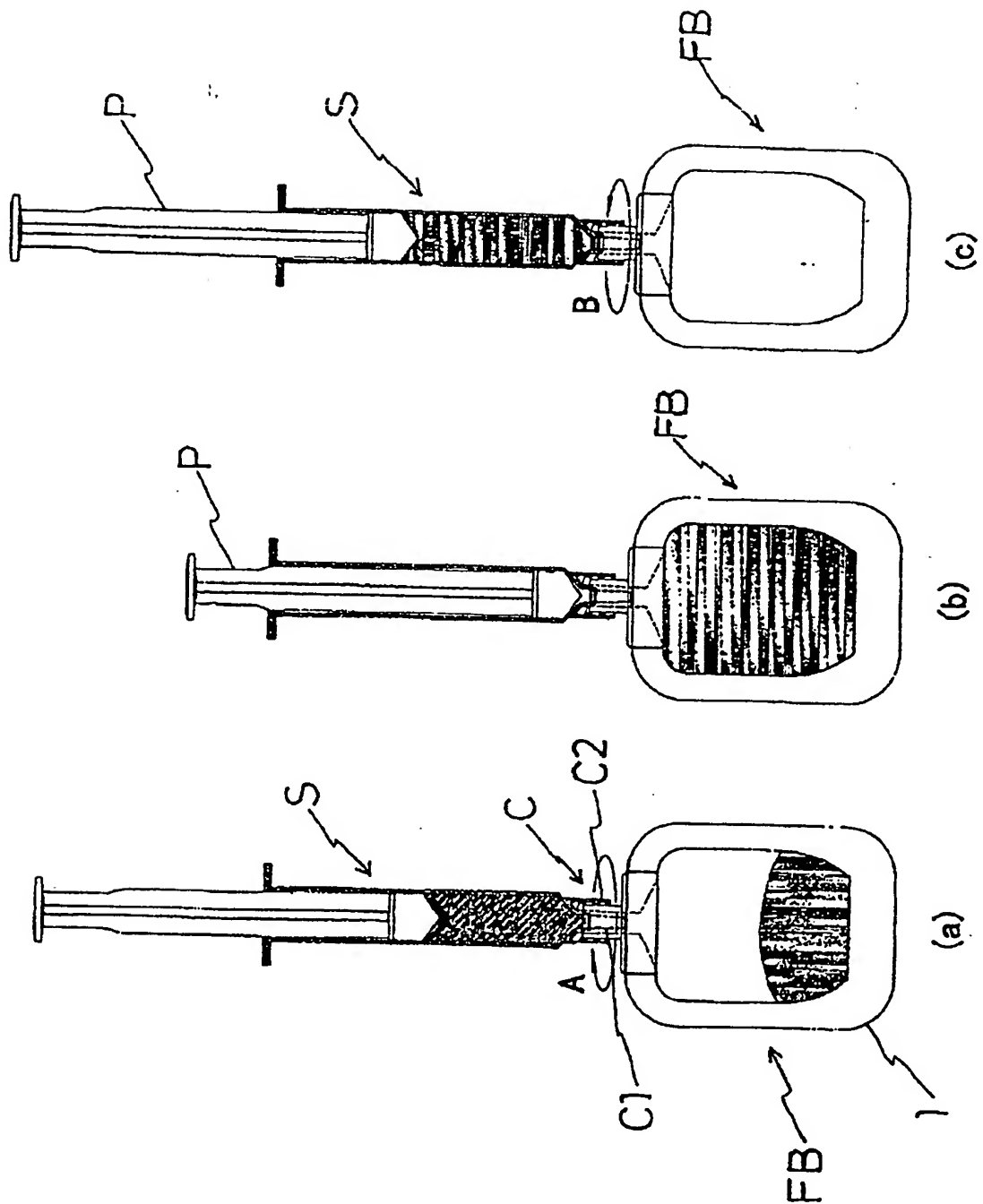
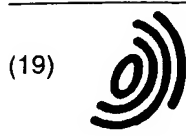


fig. 4







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(71) Applicant: **NIPRO CORPORATION**  
**Osaka-shi Osaka 531 (JP)**

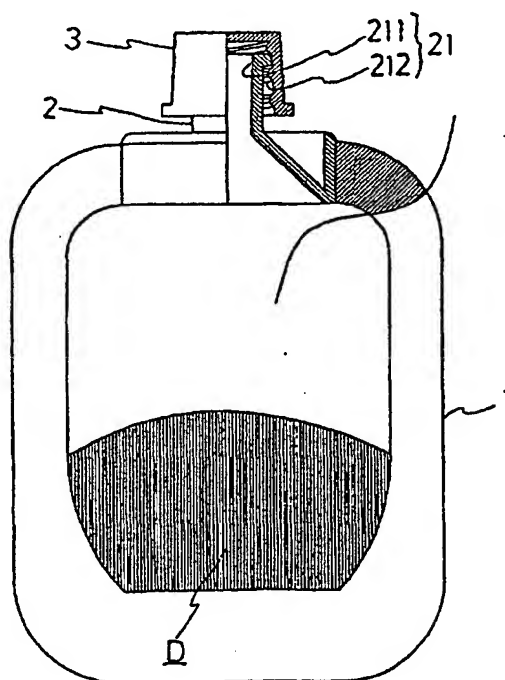
(74) Representative: **VOSSIUS & PARTNER**  
**Siebertstrasse 4**  
**81675 München (DE)**

(72) Inventors:  
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fig. 1





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## EUROPEAN SEARCH REPORT

Application Number  
EP 02 02 4446

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TECHNICAL FIELDS SEARCHED (Int.Cl.7)					
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The present search report has been drawn up for all claims					
Place of search <b>THE HAGUE</b>		Date of completion of the search <b>14 April 2003</b>	Examiner <b>Godot, T</b>		
<table border="0"> <tr> <td style="vertical-align: top;"> <b>CATEGORY OF CITED DOCUMENTS</b>            X : particularly relevant if taken alone            Y : particularly relevant if combined with another document of the same category            A : technological background            O : non-written disclosure            P : intermediate document         </td> <td style="vertical-align: top;">           T : theory or principle underlying the invention            E : earlier patent document, but published on, or after the filing date            D : document cited in the application            L : document cited for other reasons            &amp; : member of the same patent family, corresponding document         </td> </tr> </table>				<b>CATEGORY OF CITED DOCUMENTS</b> X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document	T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document
<b>CATEGORY OF CITED DOCUMENTS</b> X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document	T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document				

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